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November 20, 2017

The Honorable Greg Walden
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
2322A Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Walden and Ranking Member Pallone,

Public Citizen is a national consumer advocacy organization with more than 400,000 members and supporters. We advocate on an array of issue areas to advance the public interest, including ensuring prescription drugs meet high safety and efficacy standards and are made more affordable both in the U.S. and abroad.

We write to you today to express concerns with the proposal to grant two years of exclusivity for certain over-the-counter (OTC) drugs that is included in the September 11, 2017, House of Representatives' discussion draft of the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2017.

While Public Citizen supports many of the measures included in the Act that would enable the Food and Drug Administration (FDA) to better ensure that OTC drugs are safe and effective, we are concerned that the proposal to grant two years of exclusivity for certain OTC drugs could have negative repercussions for consumers.

Existing provisions of exclusivity for prescription drugs have led to an array of anti-consumer behaviors from the prescription drug industry resulting in negative impacts on consumers. While many of the worst outcomes relating to prescription drug exclusivities may not apply, or would at the very least be muted in the OTC drug context, we are opposed to the further proliferation of exclusivity provisions and call for their removal from the Act.

As the committee moves forward with developing this legislation, it should consider what tactics companies may engage in to shift patients towards more expensive, exclusivity-protected products and stymie the availability of lower-cost therapeutic alternatives.

1) Will companies limit the availability of older but equally effective products after receiving exclusivity protection for a new OTC drug product?

Under the discussion draft of the Act, a company could gain a period of exclusivity for a new OTC medicine that demonstrates no increased clinical benefit compared to an old medicine. Under such a

scenario, might they cease selling the older product and only seek to stock store shelves with the newer, more expensive product?

2) Will drug companies be able to extend their effective exclusivity periods beyond an initial grant of two years?

In the prescription drug context, companies sometimes engage in a practice known as 'product hopping,' wherein a drug company makes efforts to prolong its monopoly period by making a minor change to a medicine as its monopoly protections are nearing expiration in order to receive a new period of monopoly protection for the 'new' product, and then ceasing to market the old product, effectively prolonging its exclusivity period.

3) Will the granting of exclusivities for OTC drugs lead to increased direct-to-consumer advertisements?

In the prescription drug context, DTC advertisements are utilized routinely by industry to steer consumers towards medicines that are more expensive than other products for a given condition without delivering any increased clinical benefit. Providing monopoly protections for OTC drugs could lead to similar attempts to negatively influence consumer behavior.

Moreover, while Public Citizen does not believe that any exclusivity provision for OTC drugs should be included in the Act, even if one accepted the rationale for inclusion of exclusivity, we believe that the scope of what activity results in exclusivity is overly broad and that the length of exclusivity is excessive.

The Act provides for two years exclusivity when an OTC drug has a new active ingredient or when there is a change in conditions of use of an OTC drug that requires original human data studies. The Act defines 'human data' as "data from any testing with human subjects, including clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics, bioavailability, label comprehension studies (including self-selection studies), or human factors." Conducting a label comprehension study, for example, would be an extremely low bar to qualify a company for the receipt of such a generous reward.

Thank you for your attention to this issue and your efforts to reform OTC regulations.

Sincerely,

Michael Carome, Director of Health Research Group, Public Citizen
Eagan Kemp, Health Care Policy Advocate, Public Citizen
Steven Knievel, Access to Medicines Advocate, Public Citizen

CC: The Honorable Michael Burgess
The Honorable Diana DeGette
The Honorable Debbie Dingell
The Honorable Gene Green
The Honorable Brett Guthrie
The Honorable Robert Latta